§170.315(f)(5) Transmission to public health agencies – electronic case reporting

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

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§170.315 (f)(5) *Transmission to public health agencies – electronic case reporting*—

(i) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(ii) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(iii) *Case report creation.* Create a case report for electronic transmission:

(A) Based on a matched trigger from paragraph (f)(5)(ii).

(B) That includes, at a minimum:

(1) The data classes expressed in the standards in § 170.213, and in accordance with § 170.205(a)(4) and (5), or

(2) The Common Clinical Data Set in accordance with § 170.205(a)(4) for the period until May 2, 2022.

(3) Encounter diagnoses. Formatted according to at least one of the following standards:

(i) The standard specified in §170.207(i).

(ii) At a minimum, the version of the standard specified in §170.207(a)(4).

(4) The provider's name, office contact information, and reason for visit.

(5) An identifier representing the row and version of the trigger table that triggered the case report.

Standard(s) Referenced

Paragraph (f)(5)(iii)

§ 170.213 United States Core Data for Interoperability (USCDI)

§ 170.205(a)(4) Health Level 7 (HL7®) Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).

§ 170.207(a)(4)International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2019 Release

§ 170.207(i) Encounter diagnoses: The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions ICD-10-CM as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

Certification Companion Guide: Transmission to public health agencies – electronic case reporting (Cures)

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC

Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(5). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(f) "paragraph (f)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (f) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging", which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - End-user device encryption (§ 170.315(d)(7))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.
- A specific content exchange standard for electronic case reporting (eCR) is not required to meet this criterion. [80 FR 62667]

- This criterion may be met through one of the following two ways:
- - Documentation that sufficiently describes how the Health IT Module meets the functional requirements of the criterion.
  - Documentation of participation in an initial eCR implementation as part of the Digital Bridge initiative (http://www.digitalbridge.us) and the ability to meet paragraph (i) of this criterion.
- The optional use of an ONC-approved test tool for case reporting using standards such as Consolidated- Clinical Document Architecture (C-CDA), the Structured Data Capture (IHE SDC) Implementation Guide, or the Fast Health Interoperability Resources (FHIR) Structured Data Capture Implementation Guide. While not required to meet this criterion, testing through an ONC-approved test tool for case reporting would meet the requirements of this criterion.

Paragraph (f)(5)(i)

Technical outcome – A Health IT Module is able to consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to a public health agency.

Clarifications:

- An example table of trigger codes is in "Trigger Code Table Examples" under the Reference Documents section on the Test Procedures tab.

Paragraph (f)(5)(ii)

Technical outcome – A Health IT Module can match information recorded in a patient visit or encounter to a trigger code in the trigger code table.

Clarifications:

- No additional clarifications available.

Paragraph (f)(5)(iii)

Technical outcome – When a trigger is matched in accordance with provision (f)(5)(ii), the Health IT Module electronically creates an initial case report with the following subset of USCDI Data

Elements:

- Patient Demographics: First Name
- Patient Demographics: Last Name
- Patient Demographics: Birth Sex
- Patient Demographics: Date of Birth
- Patient Demographics: Race
- Patient Demographics: Ethnicity
- Patient Demographics: Preferred Language
- Problems: Problems
- Medications: Medications
- Laboratory: Tests
- Laboratory: Values/Results
- Vital Signs: Diastolic blood pressure
- Vital Signs: Systolic blood pressure
- Vital Signs: Body height
- Vital Signs: Body weight
- Vital Signs: Heart rate
- Vital Signs: Body temperature
- Vital Signs: Pulse oximetry
- Vital Signs: Inhaled oxygen concentration
- Vital Signs: BMI percentile per age and sex for youth 2-20
- Vital Signs: Weights for age per length and sex
- Vital Signs: Occipital-frontal circumference for children <3 years old
- Procedures: Procedures
- Care Team Members: Care Team Members
- Immunizations: Immunizations
- Assessment and Plan of Treatment: Assessment and Plan of Treatment

Clarifications

- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards [80 FR 62612-13]:
  - SNOMED CT® OID: 2.16.840.1.113883.6.96
  - LOINC® OID: 2.16.840.1.113883.6.1
  - RxNorm OID: 2.16.840.1.113883.6.88
  - HL7 Standard Code Set CVX-Vaccines Administered OID: 2.16.840.1.113883.12.292
  - National Drug Code Directory OID: 2.16.840.1.113883.6.69
  - International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) OID: 2.16.840.1.113883.6.4
  - CDC Race and Ethnicity Code Set Version 1.0 (March 2000) OID: 2.16.840.1.113883.6.238
  - Tags for Identifying Languages—Request for Comment (RFC) 5646 (preferred language) OID: 2.16.840.1.113883.6.316
  - Healthcare Provider Taxonomy OID: 2.16.840.1.113883.6.101
- A Health IT Module can present for testing and certification to more recent versions of the following vocabulary standards than the versions adopted in the 2015 Edition Final Rule [80 FR 62612]:
  - SNOMED CT®
  - LOINC®
  - RxNorm
  - CVX
  - NDC
  - CDC Race Ethnicity Code Set
- The requirement for an identifier representing the row and version of the trigger table that triggered the case report in (f)(5)(iii)(B) can be met by providing an identifier that will uniquely identify the original file from which the “matched trigger” described above originated (the version of the trigger table) as well as uniquely identify the individual trigger (row) itself.

Content last reviewed on June 22, 2020